



K100-0106 E-Z Chek® Sensitive Total Chlorine Test Strips
K100-0118 (/F) Ultra-Low™ Total Chlorine Test Strips
Important Application Note

Introduction

Testing to determine levels of chloramines and/or free chlorine in water used for dialysis and the rinse water of dialysis machines is required by the Centers for Medicare and Medicaid Services (CMS), water treatment system manufacturers, and dialysis machine manufacturers. CMS has adopted the Association for the Advancement of Medical Instrumentation (AAMI) recommendations. The AAMI/ANSI National Standard for Hemodialysis Systems (RD62 - 2006) lists the maximum allowable level for these contaminants. RPC’s K100-0106 E-Z Chek® Sensitive and K100-0118 (includes optional “F” color chart version) Ultra-Low™ Total Chlorine Test Strips are FDA 510k cleared for testing dialysis water for low levels of total chlorine and are widely used for this purpose.

WARNING

Levels of chloramines and free chlorine in dialysis water greater than the AAMI/ANSI maximum allowable levels (0.1 ppm chloramines and 0.5 ppm free chlorine) may cause severe injury or death to dialysis patients. Failure to follow instructions for use for the K100-0106 E-Z Chek® Sensitive, K100-0118 (/F) Ultra-Low™ Test Strips, or other analytical tests (e.g. DPD based tests) for chlorine may result in inaccurate test results.

Important Tips for Using the E-Z Chek® Sensitive and Ultra-Low Total Chlorine Test Strips

- 1) **Read carefully, the entire instructions for use (IFUs)** for the model number test strip you are using. Be sure to follow the correct IFUs for the test you are using. Procedures vary widely between test models.
- 2) **For every test, use a stop watch or second hand of a clock/watch** to make sure the dip/swish time and wait time called for in the IFUs is correct. Proper test sample exposure time and wait time are critical for test strip (and DPD assay) accuracy.
- 3) **Be aware that the color of an unused test strip** (K100-0106 or K100-0118 (/F)), right out of the bottle or foil wrap, **is not supposed to match the “zero” color** block on the bottle label or on the color card. The color of the test strip will change to match the zero color when checked (per the IFUs) in a water sample known to be free of chlorine (e.g. distilled water).
- 4) **Be aware that**, while not required by RPC for routine verification of test strips (see RPC Certi-Chek® program), **a positive control kit (part number K100-0118QC) is available** from RPC as a tool for investigative purposes. This kit will produce a reference standard of total chlorine with a known value of between 0.1 ppm and 0.15 ppm.
- 5) **Be aware that DPD total chlorine assays are not more accurate** or better when compared with RPC’s E-Z Chek® Sensitive or Ultra-Low® Total Chlorine Test Strips. Refer to the following table for a comparison.

Potential Problem areas	DPD TC Assay	K100-0106 E-Z Chek® Sensitive	K100-0118 (/F) Ultra-Low™
Interfered with by manganese	Yes	No	No
Possibility of reagent handling error	Yes	No	No
More procedural steps (> error potential)	Yes	No	No
Smaller sample size (> error potential)	Yes	No	No
FDA 510k cleared as a dialysis water test	No	Yes	Yes

- 6) **Be aware that ESRD surveyors may ask** the following question: **“How do you know** that this test is suitable for, or works properly in, this application?”. The best answer is: **“By the use of documented process control”**. **Documented process control** includes, compliance with instructions for use, training, and adherence to policies and procedures (including passing a color blindness test).